

REMARKS/ARGUMENTS

The Status of the Claims.

Claims 1, 3, 6, 11-13, 18-21, 24-26, and 73 are pending with entry of this amendment. Claims 13, 18, 19, and 24, are amended herein as suggested by the Examiner, e.g., to clarify that the agonist is administered to a patient in need of immune suppression, for which support is replete throughout the specification as filed. Claims 21 and 73 are amended herein as suggested by the Examiner to overcome the new claim objections. Applicants submit that no new matter has been added to the application by way of the above Amendment. Accordingly, entry of the Amendment is respectfully requested.

These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record.

Examiner Interview

Applicants would like to thank Examiners Woodward and Rao for the helpful interview of July 30, 2008, which served to establish the differences between the prior art and the claimed invention and clarify the remaining issues blocking allowance. These issues are each discussed in detail below.

The Priority Claims are Proper

Benefit of the filing dates of provisional application 60/444,494, filed January 31, 2003, and provisional application 60/519,074, filed November 10, 2003, was not acknowledged by the Examiner. As described in detail below, Applicants have presented a proper priority claim to both documents and respectfully request that the relevant priority claims be properly acknowledged.

For example, in provisional 60/444,494 the inventive concept that the receptor for IL-27 is involved in control of the duration and intensity of immune responses in mammals is provided, e.g., in the 2nd column on page 10, where the role of IL-27R is described and proposed as a novel target for immune suppression. See, also, page 5, and pages 9-10 further describing the discovery that the absence of IL-27R leads to immune hyperactivity. One of skill in the art would know based on this data to activate, e.g., with an agonist, IL-27R to suppress the immune system. In fact, **the abstract clearly states and the**

data fully support that the receptor is an "antagonist of T-cell mediated immune hyperactivity." Therefore, with this guidance, one of skill would know, if the receptor antagonizes or blocks immune hyperactivity, to use an agonist or activator of the receptor to suppress the immune system as claimed. These concepts and data are reiterated in the 60/519,074 provisional application, e.g., at page 3, column 2, and page 10, column 2.

With regard to both provisional applications, the claimed invention is that of using an agonist of IL-27R to suppress the immune system. This is explained in both provisional applications. The key concept embodied in the claimed invention is that activation of IL-27R can be used to suppress the immune system in contrast to the prior art's use of an agonist to activate the immune system. This concept is fully supported in the specifications of both provisional applications and described in sufficient detail to enable the full scope of the claims. Applicants therefore respectfully request that the benefit claim be acknowledged.

35 U.S.C. §112

Applicants note with appreciation the Examiner's withdrawal of rejections under 35 U.S.C. § 112.

35 U.S.C. §102.

Claims 1, 6, 11-13, 18-21, 24-26, and 73 were rejected under 35 U.S.C. §§102(a) and 102(e) as allegedly anticipated by Timans et al.; under 35 U.S.C. §102(b) as allegedly anticipated by De Sauvage et al. and by Bennet et al.; and under 35 U.S.C. §102(e) as allegedly anticipated by Matthews et al. Applicants respectfully traverse each rejection as discussed in detail below.

In order for a reference to anticipate an invention, the reference must teach each and every element of the claimed invention. Anticipation requires that "all limitations of the claim are found in the reference, or 'fully met' by it." Kalman v. Kimberly-Clark Corp., 218 USPQ 781, 789 (Fed. Cir. 1983).

Applicants note with appreciation Examiner Woodward's helpful discussion of the anticipation issues in the interview of July 30, 2008. The interview seems to have

clarified that the claimed combination of steps, i.e., selecting a patient in need of immune suppression and administering an IL-27R agonist, is not explicitly in the prior art. In summary, it was acknowledged that the prior art advocates the use of IL-27R agonists to activate the immune system and IL-27R antagonists to suppress the immune system. The claimed invention is drawn to exactly the opposite, i.e., treating a patient in need of immune suppression with an agonist of IL-17R. Although the class of compounds referred to as IL-27R agonists is known in the prior art, as well as administration of such compounds to patients; the selected patient population of the claimed invention is novel over the prior art. For example, in the prior art, such a compound would be given to a patient in need of immune activation; and in the claimed invention, a patient in need of immune suppression is selected for administration of an IL-27R agonist. The different patient population provides novelty and non-obviousness (the prior art recommended the exact opposite of what is claimed) over the prior art.

The remaining issues appear to involve determining whether the claims are a new use, a new property, an inherent property or a new method of using a known composition. For example, it must be determined whether the claimed invention is an unpatentable intended use claim or a patentable new method of using a known compound. A related issue is the issue regarding whether the claim constitutes an inherent property of a known compound. As explained in more detail below, the claimed invention is novel, non-obvious, and patentable as a novel method of using a known compound.

Clarification of previous response

Applicants would first like clarify the record regarding alleged admissions referred to in the Office Action mailed February 26, 2008.

First, on page 8 of the office action, regarding the DeSavage reference, there appears to be some confusion about Applicants acknowledgement that the term "immune disorder" includes "immune suppression". The office action seems to interpret this as some type of admission that immune disorder is the same as immune suppression, when in fact, immune suppression is only one species of immune disorder, another species being immune activation. When kept in context, it is clear that Applicants made this statement to clarify that although all the same terms and compositions are mentioned in the prior art, they are not

combined in the same manner as claimed. For example, Although DeSavauge mentions immune disorders (including activation and suppression) and IL-27R agonists and antagonists, it does not teach the use of agonists to IL-27R to suppress an immune response.

Second, in the last paragraph of page 9 of the office action and in the first full paragraph of page 10 a quotation from Applicants response is alleged to be an admission that Bennet teaches the claimed invention. However, this quote was taken out of context and the phrase "for immune suppression" was added at the end. Applicants' actual comment was as follows:

"Bennet, along with other prior art available at the time of Applicants' invention, urges the use of an antagonist of IL-27R for immune suppression and if anything only vaguely alludes to a use for an agonist of IL-27R."

The Office action referred to this comment as a vague allusion to the use of IL-27 R agonists "for immune suppression." The phrase "for immune suppression" was added by the Office but by no means does Bennet even vaguely allude to the use of IL-27R agonists "in immune suppression". Applicants would like to clarify that the vague allusion to IL-27R agonists in Bennet is to use the agonists to activate the immune system, the exact opposite of what is claimed.

Third, on page 11, there appears to be some confusion about diseases for which immune suppression might be needed. Applicants' intent with the following quote is to illustrate that a patient may be in need of immune suppression even if the patient is not suffering from what is typically considered an immune disorder.

In addition, there appears to be some confusion in the Action regarding conditions to be treated in the claimed methods verses those discussed in the prior art. In all the claimed methods, the agonist is used to suppress an immune response. A patient may be suffering from any of a wide range of disorders and be in need of immune suppression. However, the claims are amended herein, as suggested by the Examiner, to clarify which disorders are those in which immune suppression is especially desired. Therefore, the claimed invention is not anticipated by Bennet and Applicants respectfully request that the rejection be withdrawn.

This justifies the lists of diseases which are included in claims, yet still serves to distinguish over the prior art. In the prior art, a patient may have had one of the same diseases as those presently listed, e.g., in claim 21. However, in the prior art, the patient, when in need of immune activation, would be given an agonist of IL-27R. In the claimed invention, the patient, whatever disease or condition they are suffering

will only be given an agonist of IL-27R when the patient has been selected as one in need of immune suppression. As the same patient will not be in need of immune activation and immune suppression at the same time, these two patient populations do not overlap. Therefore the claimed invention is novel over the prior art.

The claimed invention is novel over the art because a different patient population is treated than that contemplated in the prior art.

The claimed invention is a new method of suppressing the immune system using IL-27R agonists. To show anticipation, the Patent Office must show that the prior art teaches a connection between activation of IL-27R and suppression of the immune system (as provided in the present application). This has not been shown by any of the references and therefore, none of the references anticipate the claimed invention.

To anticipate the claimed invention, the prior art must specify that the agonist be given to a patient in need of immune suppression. The prior art cited in the Action discusses both agonists and antagonists and list many immune disorders, including those that require immune suppression. However, the art cited, if anything, recommends agonists for immune activation and antagonists for immune suppression. This is exactly opposite to the claimed invention, which comprises selecting a patient in need of immune suppression and administering an IL-27R agonist to that patient. Therefore, the prior art does not anticipate the claimed invention. Applicants therefore respectfully request that the rejections be withdrawn.

The claims are patentable as a new method of using a known compound

The response relied on In re May to allege that the claimed invention is an intended use of a known compound and not patentable. Applicants respectfully disagree. In May, the same compound was given to the same patient population to achieve a different result. In re May and Eddy 197 U.S.P.Q. 601 (C.C.P.A. 1978). The preamble of the claims recited a new result, but the actual steps of the method claim were the same as the prior art. In the present case, the same compound is given to a different patient population and the claim is written with actual method steps that make that difference clear. The claimed invention is therefore not a mere intended use; it is an actual method that differs from that in

the prior art. The following review explains in more detail why the claimed invention is a patentable new process of using a known compound.

The patent statute makes clear in 35 U.S.C. § 101 that "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor," and 35 U.S.C. § 100 specifically states that a "process" **"includes a new use of a known process, machine, manufacture, composition of matter, or material."** (emphasis added). The presently claimed invention is a process that falls into the category of a new use for a known composition of matter and is patentable as such under 35 U.S.C. § 100 and 101.

Specifically, claim 1 is drawn to a method of treating a patient. The method comprises two steps: (1) selecting a patient in need of immune suppression; and (2) administering to said patient an effective amount of an IL-27R agonist. (Please note that all other claims rely on these two steps also and so the same argument applies to all claims) These two steps are not found together in any of the prior art. In the prior art, immune suppression is treated with an IL-27R antagonist and IL-27R agonists are used to activate the immune system. This is exactly the opposite of what Applicants claim. Applicants therefore claim a new method of using IL-27R agonists.

The proper, allowed manner of claiming a new use of a known composition is well established in case law. See, e.g., In re Fong, Ward, and Lundgren 129 U.S.P.Q. 264 (C.C.P.A. 1961), which makes clear that a new use for a known composition is patentable when directed to a **process**. In Fong, a new use for a soil-suspending agent was claimed as a process of removing soil from a textile comprising the step of washing the material with the compound. Fong, 129 U.S.P.Q. 264, 266. This is analogous to the presently claimed invention which is claimed as a process of treating patients comprising the steps of selecting a particular patient population and administering the known compound. In Fong, the compound had not been used to wash fabric in the prior art; and in the present case the compound has not been used in the prior art to treat the patient population selected, i.e., those in need of immune suppression.

In contrast, an intended use is not patentable as shown in In re Pearson 181 U.S.P.Q. 641 (C.C.P.A. 1974). In Pearson, Applicants attempted to patent a new use of a

known compound for treatment of peanut plants. The new use was applying the compound to the leaves of the plant as opposed to the soil around the plant. However, in this case, the court found that prior art methods of use had actually involved applying the compound to the leaves and the entire plant even though the intended application site was the soil. Therefore, the court ruled that the claim was invalid because the new use differed from the old use only in intent, that there were in fact, no differences between the claimed step of applying the compound to the leaves and the prior art method of application in which the compound was inadvertently applied to leaves as well as the soil. The only difference was the intent regarding where to place the compound; but in both situations, the compound ended up on the leaves of the plant. This is in contrast to the presently claimed invention, in which the actual method of using the compound is different from the prior art, e.g., given to a different patient population. In the claimed invention, a known compound is administered to a different population of patients than that in the prior art (both actual and intended use are different from the prior art). In *Pearson*, the new use did not in point of fact differ from the old use. In the present case, the old use and the new use are direct opposites and do not overlap. Therefore, the claimed invention is not merely an intended use claim.

For further interpretation of the doctrine of intended use, see e.g., Ex parte Schundehutte and Trautner 184 U.S.P.Q. 697,698 (Pat Office Board of Appeals 1974) and In re Paulsen 31 U.S.P.Q.2d 1671,1673 (Fed. Cir. 1994), which both discuss the preamble in terms of intended use. For example, in Schundehutte, the preamble, "a reactive dyestuff of the formula . . ." was read as a limitation on the claim, not as merely an intended use. In Paulsen, it was more fully explained that preambles serve as limitations when they give meaning to the claim and that a patent should be viewed in its entirety to determine whether such language was merely intended use or a limitation. In the present, case, although it has been alleged that the administering of an IL-27R agonist to a patient in need of immune suppression is mere intended use and not a patentable process describing a new use of a known compound, it is clear that the method contains an actual limitation that gives meaning to claim, e.g., the step of selecting a patient population that differs from the patient population in the prior art.

For more information on the patentability of a new use of a known compound, please see Chisum § 1.03[8][c] which explains very clearly that a product or composition may not be patented for a new use of a known compound, but **a process that is altered from the original process for that compound may be patented**, e.g., meets the standards of novelty and non-obviousness. It is explained that the new use is patentable as a process as long as it is novel and non-obvious over the old process. The claimed invention in the present application is a new use of a known compound that is claimed as a process that includes steps not present in the prior art, i.e., the selection of a patient in need of immune suppression. As the prior art process is exactly the opposite of the claimed process, it is not analogous to any previously known method and cannot be considered anticipated by or obvious over the prior art.

Finally, in Catalina Marketing International, Inc. v. Coolsavings.com, Inc., 289 F.3d 801 (Fed. Cir. 2002), the Federal Circuit discussed the principles of intended use and patenting a new use of an old compound and confirmed that this "principle does not mean that apparatus claims necessarily prevent a subsequent inventor from obtaining a patent on a new method of using the apparatus where that new method is useful and nonobvious." (289 F.3d at 809). The federal circuit elaborated on this point with a hypothetical that clearly shows the presently claimed invention to be a patentable new method of using a known compound.

"Perhaps a hypothetical best illustrates these principles: Inventor A invents a shoe polish for shining shoes (which for the sake of example, is novel, useful, and non-obvious). Inventor A receives a patent having composition claims for shoe polish. Indeed the preamble of these hypothetical claims recites "a composition for polishing shoes." Clearly, Inventor B could not later secure a patent with composition claims on the same composition because it would not be novel. See In re Schreiber, 128 E3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). Likewise, Inventor B could not secure claims on the method of using the composition for shining shoes because the use is not a 'new use' of the composition but, rather, the same use—shining shoes. See Bristol-Myers, 246 F.3d at 1375; In re King, 801 R2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986). Suppose Inventor B discovers that the polish also repels water when rubbed onto shoes. Inventor B could not likely claim a method of using the polish to repel water on shoes because repelling water is inherent in the normal use of the polish to shine shoes. Id. at 1326 (' "[I]f a previously patented device, in its normal and usual operation, will perform the function [claimed] in a subsequent [] process patent, then such [] process patent [is] . . . anticipated by the former patented device." ') (quoting In re Ackenbach, 45 F.2d 437, 439, 7 USPQ 268, 270 (CCPA 1930)); see also Bristol-Myers, 246

F.3d at 1375. In other words, Inventor B has not invented a 'new' use by rubbing polish on shoes to repel water... Upon discovering, however, that the polish composition grows hair when rubbed on bare human skin, Inventor B can likely obtain method claims directed to the new use of the composition to grow hair. See 35 U.S.C. § 101 (1994) ('Whoever invents or discovers any new and useful process . . . may obtain a patent therefor.');

35 U.S.C. § 100(b) (1994) ('The term "process" means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.'). Hence, while Inventor B may obtain a blocking patent on the use of Inventor A's composition to grow hair, this method patent does not bestow on Inventor B any right with respect to the patented composition. Even though Inventor A's claim recites 'a composition for polishing shoes,' Inventor B cannot invoke this use limitation to limit Inventor A's composition claim because that preamble phrase states a use or purpose of the composition and does not impose a limit on Inventor A's claim." 289 F.3d at 809-810.

By applying the scenarios of the Federal Circuit's hypothetical to the present claims, it can easily be seen that the claims are patentable. A generic claim to IL-27R agonists would not be patentable (same composition as prior art). A claim to using IL-27R to activate the immune system is not patentable (same use as prior art). A claim drawn to administering an IL-27R agonist to a patient in need of immune activation for another use, e.g., to cure acne, may not be patentable (Same as Inventor B using shoe polish on shoes to repel water, equivalent to using IL-37 agonists in same population to achieve different, but inherent, result; same compound applied to same substrate or patient population) However, a claim to administering an IL-27R agonist to a patient in need of immune suppression is a new use of a known composition comparable to the method of using the shoe polish to grow hair (using the shoe polish on the skin to grow hair is equivalent to using the IL-27R agonists in patient in need of immune suppression). The selection of a novel patient population for receipt of the agonists makes it a novel method. Therefore, the presently claimed invention is patentable according to reasoning of the Federal Circuit in 2002 in Catalina Marketing.

The claims are not inherently anticipated

Another issue that seems to concern the office is the possibility that the claimed invention is anticipated based on inherency. See, e.g., M.P.E.P § 2112. Most of the case law and M.P.E.P discussion on inherency relate to composition of matter claims (not

process claims). A new undiscovered and/or unrecognized property of a composition does not make the composition patentable. M.P.E.P § 2112. However, a process of using the compound with different manipulative steps is patentable. To anticipate by inherency, the unknown property must necessarily be present in the prior art. In the case of the claimed methods, the step of selecting a patient in need of immune suppression and administering an IL-27R agonist to that person is not actually present or inherently present in the prior art. The property of selecting a particular type of patient for receipt of the known composition is not present in the prior art inherently or in fact. There is a manipulative step present in the claimed methods that is not present in the prior art and therefore the claims are not anticipated by inherency. Although the discovery of a new use for IL-27R agonists does not render the class of compositions patentable, the new method of using them is patentable.

There is a difference between recognizing a new result and taking a new action. If Applicants claimed a method of treating a person in need of immune activation by administering an IL-27R agonist, but with better or different results than previously achieved, that would be anticipation by inherency (mere recognition of a new result). In the present case, the patient population being treated is different, and therefore, no inherent administration of an IL-27R agonist to a person in need of immune suppression exists. See, Ansonia Brass & Co. v. Electric Supply Co. 44 U.S. 11 (Sup. Ct. 1892) in which a method for insulating wires to achieve noncombustible wire was not valid over a prior method of insulating wire with the exact same materials to insulate from moisture. A composition or product claim to a new advantageous property for an old product can be blocked by an inherent property in the old product, but a process claim with different manipulative steps is not anticipated by the old product. See, General Electric v. Jewel Incandescent Lamp, 67 U.S.P.Q. 155 (Sup. Ct. 1945); and Carnegie Steel Co. v. Cambria Iron Co. 185 U.S. 403 (Sup. Ct. 1902). The presently claimed novel manipulative step is that of "selecting a patient in need of immune suppression," e.g., taking a novel step to invent a new method of suppressing the immune system in a patient.

There also seems to be some concern that the immune suppression property of IL-27R is a natural property that is unpatentable. Even if, for the sake of argument, natural IL-27R agonists are considered to have an inherent ability to suppress the immune system in

the body, the method as claimed is not inherently anticipated. For example, the step of selecting a patient in need of immune suppression and administering a dose of an IL-27R agonist to that person is not present in the prior art, either explicitly or inherently.

"Anticipation by inherent disclosure is appropriate only when the reference discloses prior art that must *necessarily* include the unstated limitation, [or the reference] cannot inherently anticipate the claims," "Anticipating subject matter must be known and the knowledge must be sufficient to place enabling information in the possession of the public." In re Omeprazole Patent Litigation 82 U.S.P.Q. 1643,1654 (Fed. Cir. 2007). There is nothing in the prior art that would enable, encourage, or suggest to one of skill that a dose of an IL-27R agonist should be given to a patient in need of immune suppression. Therefore, the claimed invention cannot be inherently anticipated.

A review of the inherency doctrine in Chisum § 3.03 makes clear that this doctrine does not apply to the claimed invention. For example, as stated by the Federal Circuit in Glaxco Inc. v. Novopharm Ltd. 34 U.S.P.Q. 2d 1565 (Fed. Cir. 1995), "A claim is anticipated and therefore invalid only when a single prior art reference discloses each and every limitation of the claim . . . The disclosure need not be express, but may anticipate by inherency where it would be appreciated by one of ordinary skill in the art." 34 U.S.P.Q. 2d 1565, 1567. No one of skill in the art would select a patient in need of immune suppression and administer an IL-27R agonist to that patient based on what is in the prior art, individually or in combination. Therefore, the claim invention is not expressly or inherently anticipated by the prior art.

Non-Statutory Obvious-Type Double Patenting

Claims 1, 6, 11-13, 18-23, and 73 were provisionally rejected for alleged non-statutory obvious-type double patenting over claims 21-24 and 26-28 of copending application 11/880,121. The Examiner requested that a terminal disclaimer be filed under 37 C.F.R. § 1.321(c) or (d). When all substantive issues have been resolved and the claims are otherwise in condition for allowance, Applicants will submit a terminal disclaimer over the claims of USSN 11/880,121 if it is still necessary at that time.

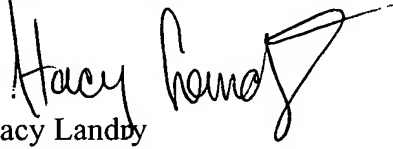
CONCLUSION

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, a telephone interview with the Examiner is hereby requested. Please telephone the undersigned at (510) 337-7871 to schedule an interview.

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Attachments:

- 1) A petition to extend the period of response for 3 months;
- 2) A transmittal sheet;
- 3) A fee transmittal sheet;
- 4) A receipt indication postcard.